REMARKS

This amendment is in response to the Office Action, dated August 29, 2007 ("Office Action"). It is respectfully submitted that the application is in condition for allowance. Claims 14-28, 33 and 34 were pending. Claims 14, 16, 19, 21, 27 and 33 have been amended; claims 27-28 and 33-34 have been withdrawn; and Claim 35 has been added by virtue of the present amendment (Claims 1-13 and 29-37 were previously canceled). No new matter has been added. Allowance and reconsideration of the application in view of Applicants' amendment and the ensuing remarks are respectfully requested.

An Interview was conducted with Examiner Chu On October 11, 2007, in which Applicants' counsel, Linda Truong, requested clarification regarding the objection to the Abstract. Ms. Truong informed Examiner Chu that the Abstract he viewed was published on the first page of the PCT application. As such, the page contained bibliographic data. Examiner Chu indicated that since the Abstract was published on the first page of the PCT Publication, it is acceptable to have the Abstract on the same page as the bibliographic data. Examiner Chu requested that Applicants note this in their response to the Office Action and he will withdraw the objection.

The Specification has been amended to remove "New" from the title.

Claims 14, 19, 27 and 33 have been amended to recite that "n" represents the integer 1, rather than "zero or the integer 1."

Claim 16 has been amended to remove compounds wherein "n" would represent the integer zero.

Claim 19 has been amended to recite that that the pharmaceutical composition is for treating a disease that is "based on PARP activation and/or are caused by Reactive Oxidative Species (ROS) and Reactive Nitrogen Species (RNS)," and that the pharmaceutical composition also comprises "a pharmaceutical additive." Support for this amendment may be found in the specification on pages 11-12.

Claim 21 has been amended to remove compounds wherein "n" would represent the integer zero.

Claim 35 has been added to recite that the disease treated by the pharmaceutical composition of claim 19 "is selected from the group consisting of coronary disease, ischemia, inflammation, unfavorable reaction in the course of radiotherapy or chemotherapy, and combinations thereof." Support for this amendment may be found in the specification on page 11.

The Examiner confirmed that Applicants' Information Disclosure Statement, filed on July 13, 2007, was considered. Applicants thank the Examiner for returning an initialled copy of the PTO/SB/08a Form.

The Examiner also reviewed Applicants' claim of priority under 35 U.S.C. §371 to International Application No. PCT/HU04/00043, filed on April 27, 2004, which in turn claims priority to Hungary Patent Application P0301154, filed on April 28, 2003. Applicants thank the Examiner for confirming that the aforementioned claim of priority is recognized.

In the Office Action, the Examiner acknowledged Applicants' (corrected) election of Group II (claims 14-28 (in part)) where Y is a valency bond and n is interger 1, and the species 2-(2,2,6,6-tetramethyl-1,2,3,6-tetrahydro-pyridin-4-yl)-1*H*-benzimidazole 4-carboxylic acid amide (*i.e.*, Compound 19 from the Table included in the specification) made during the telephone interview conducted on August 14, 2007. The Examiner indicated that Group X (Claims 33-34) is subject to rejoinder when the product claims are found allowable. Claims 27-28 and 33-34 were withdrawn from further consideration as being directed to nonelected subject matter. In addition, subject matter in claims 14-26 that differs in scope from the election was deleted.

In the Office Action, the specification was objected to on several grounds.

First, the Examiner objected to the first paragraph of the specification as not containing continuity data to which the instant application claims benefit from.

Applicants respectfully direct the Examiner to the Preliminary Amendment filed with the Patent Office on October 20, 2005. Contained therein is an amendment to the specification to include continuity data, which was recognized by the Examiner as indicated in the present Office Action.

Second, the Examiner objected to the title for containing the term "New." As shown in the "Amendment to the Specification" section of the present Amendment, Applicants have removed the term "New" from the title.

Third, the Examiner objected to the abstract "because the sheet or sheets presenting the abstract may not include other parts of the application or other material." Applicants respectfully note that the abstract viewed by the Examiner was published with the first page of the PCT Publication. As such, the additional material noted by the Examiner is the bibliographic data published with the PCT application. Applicants respectfully submit that the Abstract is acceptable and request Examiner to withdraw this objection.

In the Office Action, the claims were objected to on several grounds.

Claims 19-24 were objected to under 37 C.F.R. §1.75 as being substantially duplicative of Claim 2. Applicants respectfully note to the Examiner the Preliminary Amendment filed with the Patent Office on October 20, 2005, wherein Claims 1-13 were canceled. However, Applicants suspect that the Examiner intended to object to these claims as being substantially duplicative of Claim 14. As such, Claim 19 has been amended to recite that the pharmaceutical composition also comprises "a pharmaceutical additive." Accordingly, Applicants respectfully request the Examiner to withdraw the objection under 37 C.F.R. §1.75.

Claims 14-26 were objected to for containing elected and non-elected subject matter. Claims 14 and 19 have been amended in that "n" no longer represents the integer "zero" and only represents the integer "1" in accordance with the Election. Claims 16 and 21 have been amended to remove compounds wherein n would represent the integer zero. Accordingly, Applicants have removed the non-elected subject matter from Claims 14-26 as shown in the listing of claims above and request the Examiner to withdraw the objection.

The Examiner rejected Claims 19-23 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Examiner asserted that the phrase "a disease which can be favorably influenced by PARP inhibition and/or scavenging oxidative stress" is not described in the original disclosure. Examiner asserted that "the specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention." Applicants respectfully traverse this rejection.

Applicants respectfully submit that claims 19-23, as amended, comply with the written description requirement. Claim 19 has been amended to recite that that the pharmaceutical composition is for treating a disease that is "based on PARP activation and/or are caused by Reactive Oxidative Species (ROS) and Reactive Nitrogen Species (RNS)." The Specification, on page 11, provides the written description to support the amendment. Additionally, the specification identifies "coronary diseases, ischemia, inflammation...enhance killing of tumour cells on the course of radiotherapy or chemotherapy" as examples of such diseases. (See Specification, page 11, last paragraph.) In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

The Examiner also rejected Claims 14-26 under 35 U.S.C. §103(a) as being unpatentable over Lubisch *et al.* (U.S. Patent No. 6,448,271). Examiner found that Lubisch *et al.* disclosed the following as a class of compounds used as a PARP inhibitor:

Specifically, Examiner found that the following compound was disclosed as a PARP inhibitor.

Examiner stated that the difference between Lubisch *et al.* and the compounds claimed in the present application is that Lubisch *et al.* taught "the specific compound having piperidine bonded to the 2-position on the benzimidazole, but that compound does not have methyl groups substituted at 2- and 6-positions." Examiner further stated that Claim 3 of Lubisch *et al.* "specifically define that A may be piperidine and substituted with C₁-C₄alkyl." Examiner concluded that one skilled in the art would have found the presently claimed compounds obvious because the difference was that the "instantly claimed compounds is –CH₃ substituted piperidine vs. the –H substituted piperidine, which was suggested by [Lubisch *et al.*] as being C₁-C₄alkyl of "R³" for the same utility PARP inhibitor." Applicants respectfully traverse this rejection.

Applicants respectfully submit that Lubisch *et al.* does not render obvious Claims 14-26. Lubisch *et al.* only teaches a single substitution on the piperidine. Lubisch *et al.* does not teach or suggest using a <u>tetra</u>methyl substitution on the piperidine ring. As disclosed in the Specification, this tetramethyl substitution is important because sterically hindered amines and their oxidized derivatives are capable of antioxidant function. (*See e.g.*, Specification, page 4.) As such, the presently claimed compounds not only possess the ability to inhibit PARP, they also posses antioxidant functions.

In light of the above remarks, Applicants respectfully request reconsideration and withdrawal of this rejection under §103(a).

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If for any reason Examiner finds the application other than in condition for allowance, Examiner is requested to call either of the undersigned attorneys at the Los Angeles telephone

number (213) 633-6800 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted, Kálmán HIDEG *et al.* DAVIS WRIGHT TREMAINE LLP

Linda B. Truong

Registration No. 56,461

By

Seth D. Levy

Registration No. 44,869

865 South Figueroa Street, Suite 2400 Los Angeles, CA 90017-2566

Phone: (213) 633-6800 Facsimile: (213) 633-6899